UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff/Counterclaim Defendant, v. INTUITIVE SURGICAL, INC., Defendant/Counterclaim Plaintiff.	Case No. 3:21-cv-03496-VC

EXPERT REPORT OF JASON C. GOODWIN, MS, MPH, RN, CNOR

January 18, 2023

Highly Confidential – Subject to Protective Order

I. EXPERTISE AND QUALIFICATIONS

1. I am currently a professor of nursing at Sacramento City College as well as a surveyor for the Accreditation Association for Ambulatory Health Care (AAAHC).

2. I have served in numerous roles in operating rooms, operations, and administration of surgery programs at several hospitals and similar venues over the last 21 years. I have extensive experience with hospital regulatory mandates and industry standards regarding clinical standards of care, surgical product selection, and procedural services safety culture.

3. I received my Bachelor of Science in Nursing in 2001 from the University of Southern California, and my Masters in Public Health and Masters of Science in Nursing from the University of Massachusetts at Amherst in 2009. I have been a registered nurse since 2001 and a certified operating room nurse (CNOR) since 2016.

4. I was a Nurse Corps Officer in the U.S. Navy from 1995 through 2006. My time in the Navy included nine months deployed with the 1st Medical Battalion, Charlie Surgical Company, Forward Resuscitative Surgical Suite (FRSS) units in which I provided primary surgical trauma care on the forward edge of the Iraqi war battle area and served as a Surgical and Recovery Care Nurse on life saving surgeries for wounded Marines and Enemy Prisoners of War. I received two Navy / Marine Corps Achievement medals for developing and presenting a curriculum for shock trauma care in the forward edge of battle and for presenting and managing the education of 84 Doctors, Nurses, and Corpsmen (Medics) during the 9-month deployment.

5. I have experience evaluating and purchasing the da Vinci surgical system and related instruments and accessories, including the EndoWrist instruments, and managing a da Vinci robotic-assisted surgery program. I have supervised and been involved in the staff education of da Vinci robot surgery, including the use and reuse of the EndoWrist instruments. My first experience with the da Vinci surgical system was in approximately 2009, when I was

the operating room manager, and later Director, for Kaiser Permanente. My responsibilities in connection with the system at Kaiser included product oversight, purchasing decisions, and improving management and staff proficiency. My next role was the Director of Surgical Services and the co-chair of the robotics committee at UC Davis Medical Center. In that position, one of my duties was the administration of the health system robotics program. I was also co-chair for the committee that establishes and approves surgeon credentialing for the program, as well as the clinical requirements for continuing education and privileges. Responsibility and administration of the robotics surgical block schedule was also part of this role. I then became the Vizient Value Analysis Director for the Sutter Health Valley Region. In that role, I was tasked with establishing new Technology Value Analysis committees for all Sutter Valley Regional Medical Centers. I was intimately involved in the details of da Vinci equipment purchases, contracts, research, and evaluation of new products considered for purchase in the region. During this time, I was continuously involved in the search for safe alternatives that provided value over more expensive products. I was later promoted to the assistant procedural administrator for Sutter Roseville Medical Center, where I held more complex and senior responsibilities in the robotics program among others. Attached as **Exhibit 1** is my current curriculum vitae.

II. ASSIGNMENT AND COMPENSATION

6. I have been retained by defendant Intuitive Surgical, Inc. (Intuitive) to evaluate and respond to the Expert Report of Jean Sargent, dated December 2, 2022. I am being compensated for my time at an hourly rate of $350 for all aspects of this matter, except for deposition or trial testimony, for which I am being compensated at an hourly rate of $500. My compensation is not dependent in any way on my opinion in, or the outcome of, this matter. Attached as **Exhibit 2** is a list of my deposition and trial testimony for the previous four years.

7. The opinions rendered in this report are based on my extensive experience with, and knowledge of, the operation and administration of robotic-assisted surgery programs and the information considered in **Exhibit 3**. My statements are made to a reasonable degree of nursing certainty. I reserve the right to revise my opinions, if needed, based on new information that comes to my attention.

III. SUMMARY OF OPINIONS

8. Ms. Sargent's view that "hospitals do not consider whether FDA device approvals and clearances such as 510(k) have been obtained for servicing and repair services of instruments that are owned by the hospital" has nothing to do with whether hospitals would be willing to permit a third party without 510(k) clearance to reset Intuitive's EndoWrists for more uses than those set by the manufacturer and cleared by the Food & Drug Administration ("FDA").[1] Based on my experience working with hospitals, most hospitals or health systems will not purchase or use an altered surgical instrument that conflicts with a manufacturer's Instructions for Use (IFU) or device labeling (collectively, "manufacturer instructions") and which does not have FDA clearance.

9. Although SIS apparently found a few hospitals willing to use EndoWrists that had been reset for more usages than permitted by the manufacturer and the FDA, my experience and the record in this matter indicate that these hospitals are outliers. In fact, several doctors have testified that they would not be willing to use a non-FDA cleared item and would not expect to have access to one.[2]

[1] Expert Report of Jean Sargent, ¶ 22 (Dec. 2, 2022).

[2] Estape Dep. 59:8-22 (Oct. 22, 2022); Maun Dep. 32:11-19 (Nov. 8. 2022).

10. In Ms. Sargent's report, she suggests that hospitals rely on Group Purchasing Organizations (GPOs) to introduce new products and that hospitals will overwhelmingly "default" to the GPO product.[3] In my opinion, participation in GPOs does not impact a hospital's willingness to use a surgical instrument that conflicts with the manufacturer instructions or does not have FDA clearance. Although hospitals may rely on a GPO to review and identify new products and technologies for potential purchase, hospitals still have the ultimate choice of whether to accept and use products identified by the GPO. In my opinion and in accord with my experience, both GPOs and hospitals are responsible for ensuring that any products requiring FDA clearance have actually obtained that clearance prior to purchase and use.

11. In my opinion, concern about FDA clearance is precisely the reason why many hospitals will not use an EndoWrist beyond the use limit set by Intuitive and cleared by the FDA. The majority of hospitals and surgeon stakeholders, in my experience, view the reprocessing, repair, and/or reprogramming by third party servicing (particularly non-FDA approved) products to be inferior replacements to the OEM products.[4] Many in fact see these activities as a risk to patient safety.

IV. TRUE SERVICING AND REPAIR SERVICES TYPICALLY DO NOT REQUIRE FDA CLEARANCE

12. As an initial matter, I note that Ms. Sargent uses the phrase "servicing and repair services" for instruments, but she never defines the activities that she means to include in that term.[5] It is therefore necessary for me to define what I understand her to mean to ensure that we are talking about the same activity. In my experience working in hospital operating rooms and

[3] Sargent Rpt. ¶ 23.

[4] *Contra*. *id.* at ¶ 352.

[4] *See* Sargent Rpt. ¶ 22, 23.

[5] *See id.* ¶ 22.

administering surgical programs, servicing and repair services for instruments means returning the instrument to the manufacturer's specifications in a way that fixes a broken instrument or repairs part of the instrument. In light of my experience, I agree with Ms. Sargent that such activity typically does not require FDA clearance and is often performed by hospitals.

13. I have never referred to, nor heard someone else refer to, a substantial change to an instrument such as resetting it beyond the number of uses set by the manufacturer and cleared by the FDA as "service" or "repair." It makes no sense to me to refer to adding lives to EndoWrists beyond the number set by Intuitive as "service" or "repair." An EndoWrist that has reached its maximum number of lives is not broken or in need of repair simply for that fact alone.

14. I understand from Intuitive's FDA expert, Christy Foreman, that the fact that the hospital "owns" an EndoWrist is irrelevant to the issue of whether it can be reset without FDA clearance.[6] That is consistent with my experience. Hospitals focus on the activity for which the instrument is being used, not the fact of ownership.

15. I focus the rest of my report on the activity of resetting EndoWrists beyond the number of lives in the manufacturer instructions without FDA clearance and hospital practices regarding medical device procurement.

V. MOST HOSPITALS WILL NOT USE MEDICAL DEVICES THAT HAVE NOT BEEN CLEARED BY THE FDA, NOR USE THEM IN A MANNER THAT IS INCONSISTENT WITH THE MANUFACTURER INSTRUCTIONS OR FDA CLEARANCE

A. DEVICE LABELING AND INSTRUCTIONS FOR USE

[6] *See* Expert Report of Christy Foreman ¶ 204-14 (Jan. 18, 2023) (in *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, No. 3:21-cv-03496-VC).

16. Manufacturers of medical devices include labeling and IFUs with all medical devices. Device labeling includes not only device labels, but also instruction manuals, service manuals, and handling or storage instructions, all of which must be included in a 510(k) or pre-market notification submission.[7] Manufacturer IFUs are a specific set of instructions developed by the manufacturer, often through rigorous testing, research and development, and reviewed by FDA to ensure safe product use.[8] The FDA provides guidance to manufacturers for the "complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended."[9] With technology evolving and more complex medical devices being developed, service and repair are becoming a greater challenge. The more complex the device, the more difficult it is to use, process, and repair. The standard of care in the use and handling of surgical instruments and equipment requires adherence to these manufacturer instructions.

17. The da Vinci surgical system is a very complex medical device that comes with, and must be used in accordance with, Intuitive's extensive manufacturer instructions.[10] The user manual for the da Vinci Si system explains physical setup, orientation, power and audiovisual connection, and startup in acute detail, consistently pointing out the need to "[u]se extreme care"

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[7] *See* CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA, Labeling: Regulatory Requirements for Medical Devices, 15-17 (Aug. 1989), https://www.fda.gov/media/74034/download (section titled Labeling for Investigational and 510(k) Devices); *see also* Device Labeling, FDA (Oct. 23, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling.

[8] FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff 28-31 (2015), https://www.fda.gov/media/80265/download ("All 510(k)s must include proposed labels and labeling sufficient to describe the device, its intended use, and the directions for its use." (citing 21 CFR 807.87(e))).

[9] *See id.* at 1.

[10] *See* list of Intuitive Manufacturer Instructions in Exhibit 3, Produced Documents; da Vinci S and Si Reprocessing Instructions Appendices, PN 552268-03 Rev. B (2021).

when moving the system.[11] The Si system manual also instruct users how to properly install, insert, and remove EndoWrist instruments in conjunction with the System.[12] This manual explains that "EndoWrist instruments are valid for a predetermined number of uses," and that "[e]xpired instruments must be properly disposed of following all applicable national and local laws and guidelines."[13]

18. The Si system manual explicitly references and directs operators' attention to the manual for S/Si Instruments and Accessories and the IFUs for reprocessing those instruments.[14] The S/Si Instruments and Accessories user manual explains "[p]roper care and handling," inspection, and general cleaning requirements for safe and effective use of S/Si EndoWrists.[15] This document also makes clear that the customer's "limited license to use" the EndoWrists with da Vinci systems expires upon "expiration of the instrument's or accessory's programmed maximum number of uses."[16] The reprocessing IFUs explain in detail how to properly clean, disinfect, and sterilize Si instruments.[17] These IFUs also address cleaning methods or materials to avoid in order to prevent undue damage to the instrument, and indicate Intuitive-validated

[11] *See* Intuitive-00002201-501 at Intuitive-00002248–276; *see, e.g.*, *id.* at Intuitive-00002274 ("Use extreme care when moving or positioning the Patient Cart to ensure the arms do not hit any objects.").

[12] *Id.* at Intuitive-00002333–340.

[13] *Id.* at Intuitive-00002340.

[14] *Id.* at Intuitive-00002213 ("Note: *da Vinci Si* System users must follow all instructions for use supplied with the system, its components, instruments and accessories, including the Instruments and Accessories User Manual (PN 550675), the Reprocessing Instructions (PN 550875) and any instructions for use (IFUs) provided with instruments or accessories."); *see* Intuitive-00000501-639; Intuitive-00039624-651.

[15] *See generally* Intuitive-00000501-639.

[16] *Id.* at Intuitive-00000511-512.

[17] *See generally* Intuitive-00039624-651.

methods and materials where needed.[18] Further, the Reprocessing Instructions Appendices inform users of the maximum number of validated uses and reprocessing cycles for each EndoWrist instrument.[19]

19. Similar to the Si system manual, the manual for the da Vinci Xi system explains setup, orientation, power and audiovisual connection, and startup.[20] The Xi system manual cautions users to use the appropriate care in every process and direct users to related manufacturer instructions.[21] The document explains that "*EndoWrist* instruments are programmed for a predetermined number of uses" based on the number of times the EndoWrist is "controlled from the Surgeon Console . . . If an installed instrument does not become surgeon controlled, it may be removed without reducing the number of uses remaining."[22] The Xi system manual states that this programmed feature "ensures reliable and consistent performance throughout the *EndoWrist* instrument life."[23]

20. Like the S/Si Instruments and Accessories manual, the manual for X and Xi Instruments and Accessories explains how to properly care for, handle, inspect, and clean the X and Xi instruments.[24] This manual informs the user that the limited license to use Xi instruments

[18] *See, e.g.*, *id.* at Intuitive-00039625 (providing "Sterilization Parameters," warning against sterilization above a certain temperature, and explaining the extent of Intuitive's validation of different sterilization processes).

[19] *See generally* Intuitive-01232035-080; *see also* da Vinci S and Si Reprocessing Instructions Appendices, PN 552268-03 Rev. B (2021).

[20] *See* Intuitive-00096563-864 at Intuitive-00096591–607.

[21] *See id.* at Intuitive-00096682.

[22] *Id.* at Intuitive-00096691.

[23] *Id.*

[24] *See generally* Intuitive-00284844-945; Intuitive-00676719-840.

and accessories expires "[u]pon expiration of the instrument's or accessory's programmed maximum number of uses."[25]

21. The Xi Reprocessing Instructions and Appendices instruct users how to properly clean, disinfect, and sterilize Xi instruments.[26] These reprocessing IFUs warn users to "[u]se only the validated sterilization machines, parameters and cycles, and follow instructions in entirety," as "other cycles and parameters have not been validated and may damage the device, or may result in incomplete sterilization."[27] Further, the Appendices inform users of the maximum number of uses and reprocessing cycles for which each Xi instrument is validated.[28]

22. Resetting the EndoWrist product beyond its manufacturer-instruction-standardized number of uses risks unintended harm to patients. Dismantling and resetting these electronic instruments without Intuitive authorization or FDA clearance could increase the chance of malfunction, which is why it is a common reservation from surgeons and hospital surgery departments.[29] In my opinion, the use of products in these scenarios is a patient safety hazard and would violate the standard of care.

23. Hospitals adhere strictly to manufacturer instructions for many reasons, including safety and liability. The FDA, accreditation agencies—such as The Joint Commission and the Accreditation Association for Ambulatory Health Care (AAAHC)—and national associations, including the Association for the Advancement of Medical Instrumentation (AAMI), all emphasize that organizations should strictly adhere to manufacturer instructions when using

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[25] Intuitive-00284844-945 at Intuitive-00284853; Intuitive-00676719-840 at Intuitive-00676730.

[26] *See generally* Intuitive-00512620-739; Intuitive-02047253-232; Intuitive-02046437-478.

[27] *See* Intuitive-02047253-232 at Intuitive-02047258.

[28] *See* Intuitive-02046437-478 at Intuitive-02046443-447.

[29] *See* ASS'N OF PERIOPERATIVE REGISTERED NURSES (AORN), *Guideline for Medical Device and Product Evaluation, in* GUIDELINES FOR PERIOPERATIVE PRACTICE, Section 2.4 (2022).

medical devices.[30] This is to prevent unintended patient injury by using instructions that are the product of rigorous testing.[31] Aside from patient risk, the regulatory and legal ramifications of not adhering to manufacturer instructions can lead to regulatory citations, fines, and even legal liabilities. In my role as a surveyor for AAAHC, the discovery of such a process in the facility would result in a citation by the agency.[32]

B. FDA CLEARANCE

24. I understand that the FDA clearance process is designed to ensure the safety and effectiveness of medical devices. I understand the process involves rigorous testing and evaluation of a device that requires FDA clearance to ensure that it meets certain standards.[33]

25. EndoWrists are used with the human body and thus must be tested extensively to ensure that they are safe and effective for their intended uses. When I was involved in hospital robotics programs, I was aware that each EndoWrist was tested by Intuitive and cleared by the FDA. My understanding is that the FDA clearance process includes FDA review of the manufacturer's IFUs.

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[30] *See, e.g.*, FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff 4 (2015), https://www.fda.gov/media/80265/download; Manufacturers Instructions for Use - Expectations Regarding Access To IFUs for Medical Instruments and Devices, Joint Comm'n (Oct. 21, 2021), https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/infection-prevention-and-control-ic/000002250/ [hereinafter Joint Commission Expectations Regarding Access to IFUs]; ACCREDITATION ASS'N FOR AMBULATORY HEALTH CARE, Infection Prevention Guidance Standards 7.I.I, 7.II.J (2023) [hereinafter AAAHC Handbook].

[31] *See supra* ¶ 16 and accompanying citations; *see also* Joint Commission Expectations Regarding Access to IFUs ("Failure to follow such instructions or misuse creates significant risk to safe, quality care.").

[32] *See* AAHC Handbook 7.I.I, 7.II.J.

[33] *See* 21 C.F.R § 860.7(c)(2) (2020); FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff 28-31 (2015), https://www.fda.gov/media/80265/download.

26. As a healthcare administrator, I would not allow any instruments that require FDA clearance or premarket approval, but do not have any such clearance or premarket approval, to be used in my facilities. The hospitals I worked at would not use such a surgical instrument that has not been cleared by the FDA. The hospitals I worked at are not unique in this regard. In my opinion, most hospitals or health systems would not purchase or allow an altered surgical electronic instrument to be utilized beyond the intended usage without FDA approval. The record in this case confirms my opinion. For example, the CFO of Larkin Health testified that his hospital has a policy that a medical device that is not cleared by the FDA should not be used by the hospital.[34] Likewise, Valley Medical Center's Vice President for Perioperative, Imaging & Ancillary services testified that his hospital had never purchased any products that were not FDA cleared.[35] This aligns with testimony by Valley's Supply Chain Director, stating that Valley's policy is to only purchase a medical device requiring FDA clearance if that device actually has such clearance.[36] Franciscan Alliance's Director of Contract Administration for Surgery, Nursing and Respiratory testified that if a device required FDA clearance but did not have it, Franciscan would not purchase that device.[37] Even the third party that had a business relationship with SIS, Rebotix Repair, admitted that there are some hospitals that would not use their resetting process without 510(k) clearance.[38] This makes sense to me, because I would be skeptical of any company that claimed that its device intended for use in minimally-invasive surgery did not require any FDA clearance or premarket approval.

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[34] Early Dep. 58:13-18 (Oct. 6, 2022).

[35] Wagner Dep. 145:1-9 (Oct. 11, 2022).

[36] Teal Dep. 37:22-25, 38:15-18, 39:3-14 (Nov. 18, 2022).

[37] Schimmel 30(b)(6) Dep. 51:24-52:8 (Nov. 16, 2022).

[38] Parker Dep. 180:21-181:11 (May 4, 2021) (stating that 10 percent of Rebotix's prospective customers were "not ready" to engage with Rebotix until it acquired 510(k) clearance).

27. In my opinion and experience, many surgeons would also not be willing to knowingly use an uncleared device in surgery. Dr. Meng's report and the record in this case confirm my opinion. Dr. Meng states that he relies on the FDA's judgment and expertise, and would not use EndoWrists that had been remanufactured to extend the number of uses beyond the FDA-approved number.[39] As reflected in the record, the most prolific user of Larkin Health's da Vinci surgical systems testified that he is "not willing to do something that's not FDA approved."[40] Dr. Maun of Franciscan Alliance testified that he would not expect to have access to devices that were not cleared by the FDA.[41] The longtime chairman of the surgery department at Valley Medical Center testified that he assumed his hospital would prohibit surgeons from using instruments requiring FDA clearance but which do not actually have it, and that he had never been asked to do so.[42] Valley Medical's current Chief of Surgery similarly testified she would not use an uncleared device on a patient that required FDA clearance, and struggled to even picture that scenario.[43]

28. While patient safety is the primary factor driving hospitals to use FDA cleared devices, there are other considerations that deter hospitals from using non-FDA cleared devices. For example, hospitals and healthcare professionals may be held liable for using devices that have not undergone the proper clearance process, which could result in legal, financial, and regulatory consequences.

[39] Expert Report of Dr. Maxwell V. Meng (Jan. 18, 2023) (in *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, No. 3:21-cv-03496-VC).

[40] Estape Dep. 59:18-1 (Oct. 22, 2022).

[41] Maun Dep. 32:11-19 (Nov. 8. 2022).

[42] Burke Dep. 37:8-14, 74:20-24 (Sept. 27, 2022).

[43] Bernier Dep. 48:9-14 (Nov. 7, 2022).

29. In my experience, it would be inappropriate and highly unusual for a hospital to allow third parties to service, dismantle, remanufacture, reset, or reprogram any items beyond the original manufacturer's instructions for use. I have never encountered manufacturer instructions allowing for third party alterations without specific FDA authorization.

VI. PARTICIPATION IN A GPO DOES NOT ALTER HOSPITAL POLICIES AROUND THE USE OF UNCLEARED MEDICAL DEVICES

30. I understand SIS and Vizient, a GPO, entered a "Supplier Services Agreement" on September 1, 2016,[44] as well as a September 15, 2019 amendment related to SIS's EndoWrist reset business ("the Reset Amendment")[45] and a June 1, 2021 amendment related to SIS's EndoWrist Recovery Program.[46] I understand that Intuitive has not challenged, and is not currently challenging, SIS's Recovery Program.[47]

31. Ms. Sargent claims that these agreements between SIS and Vizient mean that hospitals who are part of that GPO would have "converted" to using reset EndoWrists.[48] I disagree with this claim.

32. Most hospitals look for ways to lower costs, but very few, if any, will do so at the expense of patient safety. In my experience with hospitals, it was not uncommon to use a general purchasing organization (GPO), although not every hospital did so. GPOs are a viable option for hospitals looking to increase buying power and reduce their cost structure through active negotiating. The GPO model is based on the premise of outsourcing these tasks to enhance

[44] SIS107399.

[45] SIS047433.

[46] SIS045231.

[47] *See* Johnson 30(b)(6) Dep. 50:13-18; Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims, *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, No No. 3:21-cv-03496-VC (ECF 75) (Dec. 14, 2021).

[48] Sargent Rpt. ¶ 57.

purchasing efficiency. Although these products are often purchased to achieve cost savings, careful analysis by both GPOs and hospitals are integral to ensure FDA compliance and patient safety. It is not uncommon for a hospital participating in a GPO to purchase products independently of the GPO or to refrain from doing business with GPO-approved third parties.

33. In my experience, patient safety and FDA compliance are of paramount importance to hospitals, whether or not the hospital purchased products through a GPO or independently. Industry-standard guidelines expect hospitals "to develop and promote a safe healthcare environment to meet the needs of patients and personnel," which include "verifying that medical devices and products used within the organization are effective and safe to use."[49] Evaluation of new products or devices takes into account patient and user safety, patient outcomes, product quality, and compliance with local, state, and regulatory requirements.[50] For these reasons, at all of my previous hospital assignments, we had specific policies regarding adherence to manufacturer instructions as well as the exclusive use of FDA-cleared products and services. These policies existed to clarify the facility's and hospital system's views on safe usage. Maintaining FDA compliance is an important component of ensuring device safety to maintain a safe healthcare environment. A hospital's participation in a GPO does not absolve it of these responsibilities.

34. Additionally, in my time at Vizient as a Value Analysis Director, it was my job to oversee the purchase of medical devices and analysis of those devices for hospitals. One of my core competencies was ensuring a product was FDA compliant or authorized prior to use, in part to satisfy hospital customer expectations that devices procured or promoted by Vizient met the

[49] ASS'N OF PERIOPERATIVE REGISTERED NURSES (AORN), *Guideline for Medical Device and Product Evaluation, in* GUIDELINES FOR PERIOPERATIVE PRACTICE, Section 2.1 (2022).

[50] *See id.* at Section 2.4.

necessary regulatory requirements. Based on my experience, a GPO recommending a non-FDA-cleared product that requires clearance could expose the GPO and hospital to liability in the event of a patient injury or product malfunction.

35. For these above reasons, based on my experience working in GPO-hospital relationships, most hospitals would expect a GPO providing or promoting a non-FDA-cleared product that requires such clearance to disclose that information to the hospital before the hospital acquires the product from the GPO. Similarly, I would expect that GPO to disclose that information whether or not the hospital specifically asks for it.

36. As discussed in the prior section, hospitals look to FDA clearance as a measure of the safety and effectiveness of a medical device. The fact that a GPO makes a service available to a hospital does not mean that a hospital will abandon its concerns with the use of a device that conflicts with IFUs or which is not cleared by the FDA.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: January 18, 2023

1/18/23

Jason Goodwin, MS, MPH, RN, CNOR

JASON C. GOODWIN, MS, MPH, RN, CNOR

PERIOPERATIVE RN LEADER / QUALITY AND SAFETY EXPERT

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I am highly skilled and decorated Veteran Nurse Corps Lieutenant, honorably discharged in 2006. An experienced RN and perioperative leader, I have successfully influenced high-quality care and service excellence since 2002. I am committed to building strong relationships and providing detailed clinical assistance. Facilitation with relevant stakeholders including C-suite healthcare administrators and Physicians has been a growing responsibility as my career progressed. An expert with quality and safety compliance regulation, I have successfully prepared teams for Joint Commission, AAAHC, Medicare, Inspector General, and State audits. I am experienced managing as many as 20 managers, 4 Lean/Six Sigma process-improvement personnel, 500 total employees, and $1.8 Billion in annual gross revenue.

Clinical Experiences include:

- ✓ Medical Surgical Nursing Educator
- ✓ Shock / Trauma Intervention
- ✓ Procedural Services
- ✓ Preoperative, Intraoperative, and Postoperative Care
- ✓ Procedural Sedation
- ✓ Clinical Educator
- ✓ Root Cause Analysis
- ✓ Quality and Safety Investigations
- ✓ Standard of Care Research
- ✓ Surgical Robotics Program Co-Chair
- ✓ Value Analysis Director

Leadership Experiences include:

- ✓ Multi-site surgical venues - UC Davis Medical Center, Kaiser Permanente
- ✓ Level 1 Trauma academic medical center – UC Davis Medical Center
- ✓ Integrated health system – Kaiser Permanente
- ✓ Military health care – Naval Hospital Camp Pendleton, Operation Iraqi Freedom
- ✓ Ambulatory Surgery and Procedural services – Alta Bates Summit Surgery Center
- ✓ Clinic management – Perioperative Medicine Clinic, Kaiser Permanente San Francisco
- ✓ Capital Construction Planning and Implementation – UC Davis Medical Center

EXPERIENCE & NOTABLE CONTRIBUTIONS

Accreditation Assoc. for Ambulatory Health Care May 2022– Present

AAAHC SURVEYOR

- Perioperative Nurse Surveyor: Responsible for conducting team surveys in ambulatory surgery centers. Per Diem.

Sacramento City College August 2021 – Present

ASSISTANT PROFESSOR, DEPARTMENT OF NURSING

- Nursing Instructor: Lecture and Clinical Rotations for last semester Sacramento Community College Students. Lectures include Emergency Disaster Nursing, Leadership and Management, and other clinical modules such as renal disease, shock, and burns.

Surgical Staff, Inc. July 2020 – Present

PERIOPERATIVE / PERI-ANESTHESIA NURSING STAFF

- Staff Nurse: Providing as needed services in Multisite, Multispecialty Surgical Care Environment. Providing Services at several Greater Sacramento Ca. venues on a Per Diem basis.

Sutter Northern Ca. Health System Roseville: March 2016-July 2020

ASSISTANT ADMINISTRATOR, PROCEDURAL SERVICES: Sutter Roseville Medical Center

- Strategic Surgical Access Expansion: Maintained dyad physician partnership resulting in surgical volume growth by over 5% annually (historically 2%) and growing net revenue at 7% during the same period. This was accomplished with optimization of staffing, block schedule management best practices, and surgeon recruitment and engagement.
- Creating Perioperative Predictive Analytics Program: Initiated monthly data driven reports tracking preoperative chart readiness, surgeon readiness with specific provider data, cancellations by reason, and overall length of stay by ASA class.
- Improved Sterile Processing / Supply Chain Systems: Led a coalition of key stakeholders to improve OR readiness, supply chain accuracy, and sterile processing quality and safety. The initiative was called the "OR Supply Chain Transformation." This project resulted in a substantial reduction in excess supply returns, more accurate procedure cards, tray readiness and visibility, reduced loss and waste, and a quality oversight infrastructure in sterile processing. As of Mar 2020, the project had saved 5% in supply expenses compared to FY2019.

Vizient / Sutter Northern Ca. Shared Services

CONSULTING DIRECTOR, VALUE ANALYSIS AND CLINICAL ENGAGEMENT

- Providing Executive Level Leadership to Perioperative, Cardiac Catheterization, and Interventional Radiology services.
- Creating Robust Clinical and Technology Evaluation Forums: Establishing Value Analysis Committees throughout the Sutter Health Northern California region. These venues were essential for reviewing, initiating, and discontinuing the use of items throughout the system that were not vetted for safety, value, and patient care improvement.

UC Davis Medical Center • Sacramento, CA • November 2013-March 2016

PERIOPERATIVE SERVICES NURSING DIRECTOR

- Large Academic Hospital System Management Oversight: Responsible for 3 surgical venues, 11 cost centers, and 7 direct reports, totaling 600 division FTEs.
- Budget and Revenue Stewardship: Steward for a perioperative division driving $1.8 Billion in annual billed revenue with a 110-million-dollar operating expense budget. Successfully managed UC Davis' FY 2017 budget resulting a 1% positive variance. Accomplished a 19% reduction in total division overtime for the most recent fiscal quarter, resulting in a savings of over $225,000 in operational expenses.
- Turnover Time Improvement: Managed a team that reduced turnover times from 62 minutes to 35 minutes at a 600 bed Academic, Level I trauma center.
- Lean / Six Sigma Improvement Projects: Sponsored initiatives for supply chain reorganization, visual board management, improving OR efficiency metrics, sterile processing quality and oversight improvement, and organization wide cascading goal implementation.
- Magnet Hospital Cultural Achievement: Maintained a culture of achievement at a U.S. News "Top 50 hospitals in the US" facility while exceeding Magnet status hospital targets.
- Talent Development: Obtained the highest percentage of Board-Certified Nurses at the UC Davis Medical Center; our operating room program helped over 73 nurses obtain their CNOR certification in 2015 -2016;

a 25% certification rate. Administered the largest OR training program on the west coast, training an average of 20 RNs per year, with a 95% retention rate at 3 years.

Kaiser Permanente 2008-2013

KAISER ROSEVILLE, PERIOPERATIVE SERVICES DIRECTOR 2011-2013

- Management Oversight: Responsible for 22 total Operating Rooms at 3 venues including an inpatient operating room, ambulatory surgery center and eye center. Also directed operations in sterile processing, PACU, PREOP, Perioperative Medicine Clinic, and GI procedures. Reporting structure included 6 direct reports and 250 FTEs.
- Innovative Perioperative Solutions: Developed an electronic "Better Book" glitch capture process in the OR that expedited systematic corrections of small process defects in daily staff work. This system gave immediate status feedback to reporting staff. Product was eventually used as a best practice throughout 20 Kaiser Permanente regional operating rooms.
- Perioperative Benchmarking: Benchmark results under my leadership in San Francisco and Roseville were stellar. All Perioperative departments exceeded industry benchmarks, including 60 minute PACU length of stay, 30 minute OR turnovers, 1% Immediate Use Sterilization rate (IUSS), and 85% on time surgery starts.

KAISER SAN FRANCISCO, OR MANAGER 2010-2011

- Management Oversight: Responsible for 12 total operating rooms including an inpatient operating room, inpatient cardiovascular operating room, hybrid interventional suite, and ambulatory surgery unit. Reporting structure included 4 direct reports and 100 FTEs.
- Breaking Isolated Department Communications: Worked to cross influence PACU, OR, and SPD using collaborative staff training, combined messaging, and visibility with staff.
- Visual Management Progress: Instituted a visual board management system using Six Sigma / Lean strategies in our departments to create awareness of problems, encourage front line solutions, and celebrate successes; a best practice used in many of the preeminent highly reliable organizations.
- Perioperative Efficiency: Perioperative departments exceeded industry benchmarks, including Day of surgery cancellation rate < 1%, 60 minute PACU length of stay, and < 1% OR Postop delays.

KAISER SAN FRANCISCO, POST ANESTHESIA CARE / SAME DAY SURGERY / ENDOSCOPY MANAGER 2008-2009

- Management Oversight: Provided front line management presence in a complex series of Post Anesthesia arenas including OR, Endoscopy, Pain Procedures, Interventional Radiology, Cath Lab, and Pulmonology. Reporting structure included 2 direct reports and 50 FTEs.
- Preoperative Clinic Model Innovation: Co-initiated the prototype for a future Kaiser Permanente perioperative medicine clinic regional model for 20 hospitals. This model used Nurse Practitioners and RNs to prep all aspects of the patient record prior to day of surgery.
- Best Practice Leadership: Championed our Highly Reliable Surgical Team (HRST) steering committee.

The Surgery Center at Alta Bates Summit • Oakland, CA • 2006-2008

PERIANESTHESIA, ENDOSCOPY, PAIN PROCEDURES MANAGER

Consistently provided high-quality nursing care across all channels in order to bolster healthcare and facilitate health plan creation. Managed post-anesthesia care unit and optimized internal productivity.

Mira Costa College LVN Program • Oceanside, CA • 2005-2006

Associate Faculty, Pharmacology and Body Systems, Online Curriculum

-Taught part time online courses using blackboard platform.

Nurse Corps Officer, US Naval Service 1995-2006

Medical Surgical RN / Education Officer• Camp Pendleton Naval Hospital • 2002-2003, 2004-2006

Received Navy / Marine Corps Achievement medal for managing the training records of 26 personnel and achieving over 800 continuing education units (CEUs) during my tenure.

Trauma OR Staff RN / Education Officer:-Iraqi Deployment: Operation Iraqi Freedom • 2003 – 2004

Deployed with 1st Medical Battalion, Charlie Surgical Company, Forward Resuscitative Surgical Suite (FRSS) units. Performed primary surgical trauma care on the forward edge of the Iraqi war battle area. Surgical and Recovery Care Nurse on life saving surgeries for wounded Marines and Enemy Prisoners of War. Received Navy / Marine Corps Achievement medal for 1) Developing and presenting a curriculum for shock trauma care in the forward edge of battle (FOB). 2) Presenting and managing the education of 84 Doctors, Nurses, and Corpsman (Medics) during the 9-month deployment.

RADIOMAN / DATA PROCESSING TECHNICIAN • U.S.S. Blueridge • Yokosuka, Japan • 1995-1997

OTHER EXPERIENCE / PROFESSIONAL ACCOMPLISHMENTS

- 2 Naval Achievement Medals
- Presidential Unit Citation, Iraqi Campaign Medal – Operation Iraqi Freedom
- 2008 Featured Speaker at 2007 ASPAN Conference | Anaheim, CA
- 2010 Kaiser Permanente Leader Recognition Supplemental Bonus Award
- 2013 IHI Pt. Safety Executive Program – Inst. for Healthcare Improvement, Boston, MA
- 2021 Featured Speaker at National Conference of OR Business Managers
  - https://screencast-o-matic.com/watch/crXrczVIU0Y
- 2021 Featured Speaker at National Conference of the American Association of Operating Room Nurses (AORN)
- 2021 Featured Speaker at the Pyrotec Beyond Clean Clinical Conference
  - https://screencast-o-matic.com/watch/crXvf0VILh7
  - http://traffic.libsyn.com/firstcase/FC_Ep2_6.mp3
- 2021 2 Appearances on the Beyond Clean / First Case podcast
  - https://podcasts.apple.com/us/podcast/the-numbers-dont-lie-using-predictive-analytics-in/id1546884788?i=1000550293491
  - http://traffic.libsyn.com/firstcase/FC_Ep3_3.mp3

EDUCATION AND TRAINING

- **UNIVERSITY OF SOUTHERN CALIFORNIA | 2001**
  - Bachelor of Science in Nursing
- **UNIVERSITY OF MASS. AMHERST | 2009**
  - Master's in Public Health and Master's of Science in Nursing
- **Registered Nurse CA BRN # 610577**

- Certified OR Nurse (**CNOR)** 2016 – Present
- Certified Post Anesthesia Nurse (**CPAN**) 2004-2016
- LEAN Performance Improvement Certification – 2013
- Certified Trauma Nurse (**TNCC**) 2002-2006

- Advanced Cardiac Life Support Certification **(ACLS)**
- Pediatric Advanced Life Support Certification **(PALS)**

AFFILIATIONS

- American Society of Perianesthesia Nurses (ASPAN)
- Association of Perioperative Registered Nurses (AORN)
- American College of Healthcare Executives (ACHE)
- American Association of Life Care Planners (AANLCP)

Exhibit 2

Date:	Case consulted:	Defense (D) or Plaintiff (P)	Clinical Matter	Firm / Attorney	State	Consulted (C) Deposition (D) Trial (T)	Case Status
Jan-18	Delena v. Presbyterian Healthcare Service New Mexico	D	Anesthesia Recovery	Rodey Law	NM	(C)	Settlement Pre Trial
Mar-19	Piper v. SIHS d/b/a Memorial Hospital of Carbondale, et al	D	Deep Vein Thrombosis SOC, Cardiac Event,	Sandborn & Phoenix	IL	(C) (D)	Settlement Pre Trial
Aug-19	DiMauro v. YNHH CT	D	Dead Flap, Transport to PACU, SOC, Foot Drop, Nerve Damage.	Donahue, Durham & Noonan	CT	(C)	Settlement Pre Trial
Sep-19	Jones v. Flores	P	Failure to rescue, CRNA / MD transport SOC	Houssire, Durant, & Houssiere	TX	(C) (D)	Settlement Pre Trial
Sep-19	York v. CCHMC	P	Positioning Injury, Nursing SOC	Lawrence Firm	OH	(C)	Settlement Pre Trial
Dec-19	Limun adv. LVSC	D	Propofol Admin, Nursing Chain of Command, D/C, ASC, p/o SOC	Cotton & Associates	NV	(C) (D)	Settlement Pre Trial
Dec-19	Montoya v. New Mexico Imaging, LCSC	D	CRPS Neurostimulator Plcmt, Positioning SOC	Riley, Shane, and Keller P.A.	NM	(C) (D)	Settlement Pre Trial
Dec-19	Robbins v. Neuhoff et al.	D	Abd Hyst, Lap Hyst, removal of cervix. Nursing SOC, Consent	Murphy & Assoc.	MT	(C)	Settlement Pre Trial
Jan-20	Cervantes and Flanigan v. XXX (Instrumentation) – Pre Complaint	D	Instrumentation Reprocessing Standards	Sgro & Roger	LV	(C)	Settlement Pre Trial
Jan-20	Larson v. Providence Health & Services - Washington	D	Retained Surgical Item	Cashion Gilmore	AK	(C)	Settlement Pre Trial
Mar-20	Packer V. Morgenstern et al.	D	Colonoscopy, Perforation, P/O call SOC, D/C, P+P	Joe Garbarino	PA	(C)	Settlement Pre Trial
Jul-20	Stewart v. BCMS	D	Orthopedic Fx table traction, SOC	Siboni &Buchanon PLLC	FLA	(C)	Settlement Pre Trial
Jul-20	Tarzian v. Sunrise Flaming Surgery Center	D	Preop SOC	McBride Hall	NV	(C)	Pre Trial
Jul-20	Harrell v. Baptist Medical Center	P	Spinal SOC / Transferring Patient SOC	Pacjic & Pacjic	FLA	(C)	Settlement Pre Trial
Dec-20	Hall v. Baptist Health, Susan Mueller, Contemporary OB-GYN	D	Retained SI C-Section	Grumley, Riley, & Stewart	KY	(C) (D)	Settlement Pre Trial
Dec-20	Hays v. Abrayo	P	Medication Administration / IM	Harris, Powers & Cunningham	AZ	(C)	Settlement Pre Trial
Jan-21	Kinney v. Jennifer K. Collins; Desrose Medical Group	P	Retained Hormone Pellets	GREGORY LAW GROUP	AZ	(C)	Settlement Pre Trial
Jan-21	Holmes v. ARH	D	Intraoperative Fall under Anesthesia	Cashion Gilmore	AK	(C)	Pre Trial
Jan-21	Spring Valley Hosp adv. Zamorano	D	Falls prevention, Call Lights	JH Cotton Law	NV	(C)	Settlement Pre Trial
Jan-21	Gloria Rodriguez v. Philip Rosenthal MD	P	Chiari's Malformation / Life Care Plan	Jeremy Dobbins Firm	CA	(C) (D)	Pre Trial
Feb-21	Thomas v. St. Vincents	P	Robotic Docking Injury	Pacjic & Pacjic	FLA	(C)	Pre Trial
Mar-21	Arrata v. Arcadia OS Center	D	Informed Consent, Procedural Sedation, Pain , Trauma	Higgs, Fletcher, Mack	CA	(C)	Settlement Pre Trial
Mar-21	Ward v. Raleigh General Hospital	D	Morcellation Injury / SOC for Hospital	Offutt Nord PLLC	WV	(C)	Settlement Pre Trial
Jun-21	Gobel v. CRMC	P	Universal Protocol, Timeout	Paul Smith	CA	(C)	Settled Pre Trial
Jun-21	Goplin v. Lutheran	P	Intraoperative Bed Fall	Jay Reinan	CO	(C)	Settled Pre Trial
Jul-21	Tarzian v. Sunrise Flamingo Surgery Center LV	D	Unintended Intraoperative Injury to Eye Lids during Breast Aug. Surgery	McBride Hall, Heather Hall	CA	(C)	Pre Trial
Aug-21	Castillo v. Beach District SC	P	RSI	Bernard and Bernard Law	CA	(C)	Pre Trial
Sep-21	O'Malley, Dicey vs. St. Peter's Surgery & Endoscopy Ctr. & Alan Samuels, M.D.	P	Endoscopy Perforation / RN failure to rescue, missing code docs	Lafave, Wein & Frament	NY	(C) (D) (T)	Trial
Sep-21	Pleaseant Valley Hospital v. Stott	P	Positioning Inj., Beach Chair Nerve Damage	The Law Offices of Kenneth Yeager	CA	(C)	Settled Pre Trial
Oct-21	Davis vs. Sabu Goerge et al.	P	MAC lack of preop testing prep	Searcy, Denney, Scarola, Barnhart, and Shipley	CA	(C)	PreTrial

Exhibit 3

Materials Considered

Case Documents

Pleadings

- Complaint, *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, No. 3:21-cv-03496-VC (ECF 1) (May 10, 2021)
- Consolidated Amended Class Action Complaint, *In re: da Vinci Surgical Robot Antitrust Litigation*, Lead Case No. 3:21-cv-03825-VC (ECF 52) (Sept. 9, 2021)
- Defendant Intuitive Surgical, Inc.'s Answer, Affirmative Defense and Counterclaims, *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, No No. 3:21-cv-03496-VC (ECF 75) (Dec. 14, 2021)

Expert Reports

- *In re: da Vinci Surgical Robot Antitrust Litigation*, Lead Case No. 3:21-cv-03825-VC
  - Expert Report of Dr. Maxwell V. Meng (Jan. 18, 2023)
  - Expert Report of Christy Foreman (Jan. 18, 2023)
  - Expert Report of Professor Einer Elhauge (Dec. 1, 2022)

- *Surgical Instrument Service Co., Inc. v. Intuitive Surgical, Inc.*, Case No. 3:21-cv-03496-VC
  - Expert Report of Dr. Maxwell V. Meng (Jan. 18, 2023)
  - Expert Report of Christy Foreman (Jan. 18, 2023)
  - Expert Report of Jean Sargent (Dec. 2, 2022)
  - Expert Report of Dr. Robert D. Howe (Dec. 2, 2022)

- *Restore Robotics LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF
  - Expert Rebuttal Report of Loren K. Smith, Ph.D. (Sep. 17, 2022)
  - Rebuttal Expert Report of Professor Christina DePasquale (Oct. 7, 2022)

- *Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-CV-02274
  - Expert Report of Sarah Parikh, Ph.D. (July 26, 2021)

Deposition Transcripts and Exhibits (SIS)

- Deposition of Keith Johnson (Oct. 27, 2022) and Exhibits
- 30(b)(6) Deposition of Keith Johnson (Oct. 27, 2022) and Exhibits
- Deposition of Greg Posdal (Nov. 1, 2022) and Exhibits
- 30(b)(6) Deposition of Greg Posdal (Nov. 1, 2022) and Exhibits

Deposition Transcripts and Exhibits (Hospital Plaintiffs)

- Deposition of Dr. Greta Bernier (Nov. 7, 2022) and Exhibits
- Deposition of Dr. Michael Burke (Sept. 27, 2022) and Exhibits
- Deposition of Mark Early (Oct. 6, 2022) and Exhibits
- Deposition of Dr. Ricardo Estape (Oct. 22, 2022) and Exhibits
- 30(b)(6) Deposition of Jose Carlos Gonzalez (Oct. 17, 2022) and Exhibits

- Deposition of Jose Carlos Gonzalez (Oct. 17, 2022) and Exhibits
- 30(b)(6) Deposition of Judith Schimmel (Nov. 16, 2022)
- Deposition of Judith Schimmel (Sept. 22, 2022) and Exhibits
- Deposition of Sandra Sosa-Geurrero (Sept. 23, 2022) and Exhibits
- 30(b)(6) Deposition of Richard Teal (Nov. 18, 2022) and Exhibits
- Deposition of John Wagner (Oct. 11, 2022) and Exhibits
- Deposition of Karen Waninger (Oct. 6, 2022) and Exhibits

Deposition Transcripts and Exhibits (*Restore Robotics LLC v. Intuitive Surgical, Inc.*, Case No. 5:19-cv-55-TKW-MJF)

- Deposition of Eugene Dickens (May 27, 2021) and Exhibits
- Deposition of Sherry Harvey (May 14, 2021) and Exhibits
- Deposition of Michael Madewell (June 11, 2021) and Exhibits
- Deposition of Kyle Marks (May 21, 2021) and Exhibits
- Deposition of Tyler McDonald (May 21, 2021) and Exhibits
- Deposition of Sarah Parikh, Ph.D. (Oct. 20, 2021) and Exhibits
- Deposition of Clifton Parker (May 4, 2021) and Exhibits
- Deposition of Amie Renee Reed (May 27, 2021) and Exhibits
- Deposition of Loren K. Smith, Ph.D. (Oct. 21, 2021) and Exhibits
- Deposition of Cairo Wasfy (May 18, 2021) and Exhibits

Deposition Transcripts and Exhibits (*Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, Case No. 8:20-CV-02274)

- Deposition of Edward Harrich (May 24, 2021) and Exhibits
- Deposition of Stacey Donovan (May 27, 2021) and Exhibits

Produced Documents

Intuitive Manufacturer Instructions

- Intuitive-00000501-639 (Intuitive Surgical Instruments and Accessories User Manual, PN 550675-06 Rev. G 2014.04).
- Intuitive-00002201-501 (da Vinci Si System User Manual, PN 550650-09 Rev. A 2014.09)
- Intuitive-00002502-876 (da Vinci Xi System User Manual, PN 551400-13 Rev. A 2019.03)
- Intuitive-00039624-651 (da Vinci S/Si Reprocessing Instructions, PN 550875-03 Rev. C 2011)
- Intuitive-00096563-864 (da Vinci Xi System User Manual, PN 551400-11 Rev. B 2018.03)
- Intuitive-00284844-945 (da Vinci Xi Instruments and Accessories User Manual, PN 551457-10_B 2016.11)
- Intuitive-00512620-739 (da Vinci Xi Instrument Reprocessing Instructions, PN 551490-09 Rev. E 2017)
- Intuitive-00670595-716 (Instruments and Accessories User Manual for da Vinci Xi and da Vinci X Systems, PN 553873-02 Rev. B 2018.03)

- Intuitive-00676719-840 (Instruments and Accessories User Manual for da Vinci Xi and da Vinci X Systems, PN 553930-04 Rev. A 2020.01)
- Intuitive-01035141 (da Vinci Xi Instrument Addendum for Automated Cleaning and Disinfection, PN 554324-01 Rev. A)
- Intuitive-01232035-080 (da Vinci S and Si Reprocessing Instructions Appendices, PN 552268-03 Rev. A 2021)
- Intuitive-02047253-232 (da Vinci Xi Instrument Reprocessing Instructions for Automated Cleaning and Disinfection, PN 554324-01 Rev. B 2021)
- Intuitive-02046437-478 (da Vinci Xi Reprocessing Instructions Appendices, PN 552246-07 Rev. A 2021)
- Intuitive-02047537-540 (da Vinci Xi Instrument Addendum, PN 554349-01 Rev. A 2020.07)

Other Produced Documents

- Intuitive-00284844-945
- Intuitive-00654768-768
- Intuitive-01163789-890
- SIS000202-204
- SIS045231-232
- SIS047433-435
- SIS106493-498
- SIS107399-442
- SIS117733-749
- SIS346267-267
- SIS357819-823
- SIS357824-837

Publications

- ACCREDITATION ASS'N FOR AMBULATORY HEALTH CARE, Accreditation Handbook For Medicare Deemed Status, Ch. 7 (2022)
- ASS'N OF PERIOPERATIVE REGISTERED NURSES (AORN), *Guideline for Medical Device and Product Evaluation, in* GUIDELINES FOR PERIOPERATIVE PRACTICE (2022)
- da Vinci S and Si Reprocessing Instructions Appendices, PN 552268-03 Rev. B (2021)
- CTR. FOR DEVICES & RADIOLOGICAL HEALTH, FDA, Labeling: Regulatory Requirements for Medical Devices, 15-17 (Aug. 1989), https://www.fda.gov/media/74034/download (section titled Labeling for Investigational and 510(k) Devices)
- FDA, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff (2015), https://www.fda.gov/media/80265/download

Other Documents

- 21 C.F.R § 860.7 (2020)
- 42 C.F.R. § 482.11 (2020)
- Device Labeling, FDA (Oct. 23, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling
- Letter from Jennifer R. Stevenson, Office of Surgical and Infection Control Devices, FDA, to Elaine Lee, Sr. Regulatory Engineer, Intuitive Surgical, Inc. (Nov. 12, 2020) ("Re: K202571")
- Letter from Mark Trumbore, Assistant Director, Division of General Surgery Services, FDA, to Rick Ferreira, President, Iconocare Health (Sept. 30, 2022) ("Re: K210478")
- Manufacturers Instructions for Use - Expectations Regarding Access To IFUs for Medical Instruments and Devices, JOINT COMM'N (Oct. 21, 2021), https://www.jointcommission.org/standards/standard-faqs/critical-access-hospital/infection-prevention-and-control-ic/000002250/